PATIENT LABELING FOR THE CERAMIC/CERAMIC TOTAL HIP SYSTEM

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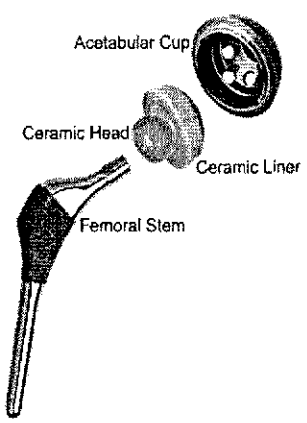
What is the Ceramic/Ceramic Total Hip System?

The Ceramic/Ceramic Total Hip System is an artificial hip joint made up of the following parts: a ceramic (alumina) ball, a ceramic (alumina) liner that fits into a metal shell; and a compatible metal hip stem that is used with these parts.



What is the purpose of the device?

The Ceramic/Ceramic Hip System is indicated for use in total hip joint replacement for the reduction or relief of pain and/or improvement in function. The device may be used in the treatment of the following conditions: inflammatory tissue disorders and non-inflammatory degenerative joint disease, including osteoarthritis, post-traumatic arthritis (secondary arthritis), and avascular necrosis.

What are the definitions for the above-mentioned conditions?

Inflammatory tissue disorders - These disorders (like rheumatoid arthritis) cause the lining covering the joints, referred to as the synovium, to become thickened and inflamed. These conditions allow too much synovial fluid within the joint space causing a chronic inflammation that damages the cartilage. This damage results in cartilage loss, pain and stiffness.

Non-Inflammatory degenerative joint disease - Is a condition that is caused by the breakdown and eventual loss of the cartilage of one or more joints. Cartilage is a protein substance that serves as a "cushion" between the bones of the joints. Non-Inflammatory degenerative joint disease includes the following three conditions listed below:

Osteoarthritis – This is often referred to as degenerative arthritis because it is a "wearing out" condition involving the breakdown of cartilage and bones. When the cartilage breaks down, the bones rub against each other, resulting in pain and stiffness.

Post-traumatic arthritis (secondary arthritis) – This type of arthritis causes inflammation of a joint resulting from an injury. The symptoms of this condition include: breakdown of the bone and rubbery tissue, bleeding in the joint space, increased thickness of the bone, flattening of the joint surface, cartilage separation from the underlying bone, and wearing away (erosion) of the bone.

Avascular Necrosis – This condition results from a loss of blood supply to the hip bones, which can lead to necrosis in portions of these bones. Without a proper supply of blood the bone's structure weakens and may collapse damaging the cartilage.

What are the contraindications of this device?

Reasons for not using this device may include:

1. An infection exists in the hip,
2. There are remote centers of infection that may be spread through the blood supply to the actual implant site,
3. Rapid joint destruction or bone loss is seen on multiple X-rays,
4. The patient's bones are still growing,
5. Patients muscles may be too weak to work properly (e.g., loss of function, fusion, or poor skin coverage around the hip joint),
6. The patient has weak bones from various causes (e.g., metabolic disorders such as Osteoporosis, Paget's disease, and Osteomalacia), which may prevent adequate support for the device.
7. The patient is unable or unwilling to follow proper procedures after joint replacement,
8. The patient weighs too much for implanted device to support the patient's full body weight, or
9. The patient is allergic to the implant materials.

What are the benefits and risks of using this device?

The potential benefits of using the Ceramic/Ceramic Total Hip replacement are the relief of pain and the improved function of your hip joint.

A two year clinical study to evaluate the Ceramic/Ceramic Total Hip System found it to be comparable, in terms of safety and effectiveness, to a marketed ceramic and plastic hip system. The study followed 479 patients who met the indications for use identified above. Two hundred and thirty seven (237) patients were implanted with the Ceramic/Ceramic Hip, and 242 were implanted with the ceramic/plastic hip. Evaluation of safety and effectiveness included comparisons of complications, x-ray results, survivorship (i.e., was the device still in place), function, and pain relief. There were complications reported but they were consistent with a marketed total hip replacement system. All patients had successful x-ray results, and 99.6% of the patients still had their device in place two years after surgery.

There is a risk that this device may not restore the hip to a condition of a normal healthy person. Activities after implanting the artificial hip may be somewhat limited.

With any surgery there are risks and complications that can arise during and after surgery. For example there may be problems with the anesthesia, development of an infection, hematoma, or hemorrhage.

Possible risks and complications associated with any total hip surgery, listed in order of severity, may include:

- death,
- myocardial infarction,
- the development of blood clots that may dislodge and cause decreased blood flow to the lungs (pulmonary embolism),
- deep vein thrombosis,
- allergic reactions,
- nerve injury, (e.g., numbness or pain),
- not being able to urinate due to pain and/or inflammation,
- swelling that continues,
- fracture of the implant,
- fracture of the bone,
- revision of the implant,
- non-union of implant and bone,
- changing position of the implant,

- dislocation of the implant,
- unequal leg lengths,
- muscle weakness
- aggravated problems in the joints of the affected limb, opposite limb, or back due to unequal leg lengths or muscle weakness,
- decreased range of motion,
- local bone resorption,
- heterotopic bone formation,
- bursitis,
- tendonitis,
- cellulitis,
- pain

Use of the ceramic liner includes the risks of the implant changing position, or the liner separating from the metal shell portion of the artificial socket. Also, there may be excessive wearing of the ceramic material, causing joint loosening and impairment of function.

The above list of risks may not be complete, and any or all risks are possible. If complications occur, you may require further hip surgery.

What procedure will the surgeon follow?

Your doctor has determined that you might benefit from a surgical procedure that replaces the hip joint with artificial parts. In this procedure, your surgeon will remove the ball portion (femoral head) of your hip and replace it with a new ceramic ball. The ball part of your new hip is attached to a long metal stem that allows your surgeon to place it firmly in the thigh bone. Your surgeon will replace the socket part (acetabulum) of your hip with a new one that fits with the new ceramic ball. The new socket is made up of the ceramic liner and metal shell.

What will I have to do before my surgery?

You will have to have routine pre-surgical tests and procedures before your replacement hip surgery, including blood tests and X-rays. Your surgeon will perform your hip surgery and take care of you throughout your surgery and healing period after surgery. The surgical procedure for this hip replacement is similar to any other hip replacement.

What are the expectations after my surgery?

You will experience discomfort following the hip surgery and the necessary rehabilitation. There are limits to what you can do after you receive your new hip replacement. Following

the surgery, you may need to use a walker, crutches, or a cane for up to three (3) months, depending upon the speed of your recovery. Your surgeon will tell you when and how much weight you should place on your new hip. After your operation, you will need physical therapy. It will not differ from other hip replacement rehabilitation. Please follow your surgeon's post surgery directions carefully. This will help speed your proper recovery during the rehabilitation period. Your surgeon will schedule the number of postoperative visits based on your ability to heal. At each visit your surgeon will examine you and ask for X-rays of your implant.

After healing has occurred, you may not be able to do the activities you did prior to your surgery (such as playing sports or heavy physical work). The device does not replace normal healthy bone. Your new hip can break or become damaged as a result of strenuous activity, trauma, or even normal use. An artificial hip has a limited expected service life, and may need to be replaced at some time in the future. Unexpected injury to the hip can cause broken bones, implant loosening, or wear of the implants.

You should contact your doctor immediately if you experience any of the following:

- excessive pain (pain that limits and or prevents normal activity),
- decrease in range of motion (post surgical range of motion will be limited; however, range of motion should increase as rehabilitation progresses. If during or after rehabilitation range of motion decreases, your doctor should be contacted.),
- swelling, or
- fever.

Are there any other devices and procedures that I could choose?

You could elect not to have surgery and choose a non-surgical method of treatment of reduced activity and medicine. You could elect to have a total hip replacement with another commercially available implant or implant part. Choices available to you include a metal femoral head and a plastic liner (metal/plastic), a metal femoral head and a metal liner (metal/metal), or a ceramic femoral head and plastic liner (ceramic/plastic). Other alternative operations may be available to you, including fusion of the hip joint. Please talk to your orthopedic doctor about these and other options.

GLOSSARY OF TERMS

Bursitis – inflammation of the bursa, a pad like sac or cavity found in the joint area and acts as a lubricant to the joints.

Cartilage – rubbery type of tissue that pads the joints

Cellulitis – inflammation of the skin around the hip due to infection

Deep vein thrombosis – the development of a blood clot in the vascular system

Dislocation - the ball at the top of the thighbone (the femoral head) is not stable within the ceramic insert

Fusion – joining together

Hematoma – collection of blood under the skin

Hemorrhage – bleeding

Heterotopic bone – formation of bone in areas in which bone is not intended to form
Inflammation – swelling, redness, and pain in tissues

Local bone resorption – the deterioration of bone affected by the surgery

Myocardial infarction – changes that occur to the heart muscle due to the lack of circulating blood (i.e., heart attack)

Necrosis – cell death

Non-union – the bone does not grow into the artificial device possibly leading to loosening

Osteomalacia - Softening of bone, particularly in the sense of bone weakened by demineralization (the loss of mineral) and most notably by the depletion of calcium from bone

Osteoporosis - Thinning of the bones with reduction in bone mass due to depletion of calcium and bone protein

Paget's disease - A chronic bone disorder that typically results in enlarged, deformed bones due to excessive breakdown and formation of bone tissue that can cause bones to weaken and may result in bone pain, arthritis, deformities or fractures

Revision – removal of the man-made devices

Printing Date